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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,189	04/21/2004	Brian S. Kelleher	028US2	7725

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/830,189	KELLEHER ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10 and 14-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 14-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/20/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 13, 2009 has been entered.

Specification

2. The disclosure is objected to because of the following informalities: Claim 6, originally filed with the specification, discloses a range from 0.5 to 32.0 mA. The current specification in Paragraph 0057 only discloses a range of 4mA to 32mA. Since the claim was originally filed, the Applicant has the ability to amend the specification to properly support the claimed subject matter. However, such an amendment to the specification will not afford the claimed subject matter the priority date of November 24, 1999, since the provisional application does not disclose the claimed range.

Appropriate correction is required.

Claim Objections

3. Claim 1 is objected to because of the following informalities: In line 13, “that” should read as “than” to be grammatically correct. Appropriate correction is required. In

line 7, “sensor electrodes” should be “electrodes" in order to properly claim the electrodes disclosed in the current specification.

4. Claims 3 and 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 3 and 4 disclose the plurality of electrical pulses comprise pulses that incrementally increase over time until an onset response is determined. Claim 1 already discloses automatically increasing the electrical stimulus in constant increments until a response is determined. Claim 1 through the use of "constant increments" already discloses a plurality of stimulus pulses.

5. Claim 27 is objected to because of the following informalities: “that” should read as “than” to be grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 5, 16 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5 discloses a claimed range of 0.5 to 4 mA. The current specification fails to support this limitation. In Paragraph 0073 of the PG Pub of the application, the range is 0.5 to 5.0 mA.

Claim 16 discloses “displaying different colors on the display when the electric current value is below a predetermined level". The current specification at Paragraph 0065 only discloses the use of a single color when a value below a baseline is measured.

Claim 28 discloses a range of “about 60mV to about 80mV”. The current specification fails to support this limitation. In Paragraph 0057 of the PG Pub of the current application, the range is disclosed as being “between 60mV and 80mV".

8. Claims 1, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 27 discloses the amplitude value greater than the predetermined value comprises a *peak-to-peak* amplitude value greater than the predetermined value. The current specification does not clearly define peak-to-peak amplitude, nor how to acquire a peak-to-peak amplitude. For instance, in order to acquire a “peak-to-peak” response, there must be a stimulus pulse train to apply electrical stimuli comprised of a plurality of

specific amplitudes; the plurality of electrical pulses would create a plurality of muscle responses, thus creating a means of measuring "peak-to-peak" amplitude. The current specification only discloses the application of a single stimulus in a “stepped fashion” that applies a single stimulus of a single current amplitude at a time, and if there is no EMG response, increasing the stimulus amplitude until there is an EMG response. Muscle response is dictated by the stimulus applied; if there is only a single electrical stimulus applied, then there will only be a single “peak” response from the muscle. Therefore the current specification fails to enable one of ordinary skill in the art to make and use the invention, since there is no way one can apply a single stimulus and be able to measure a “peak-to-peak” muscular response.

Claims 1 and 28 disclose the onset EMG value is determined when an EMG signal has an amplitude greater than a predetermined value, and the predetermined value is selected from a range of 60mv-80mV. The current specification first discloses in Paragraph 0049, a predetermined level of 60mV or 80mV, and then in Paragraph 0057, discloses the onset response value is between 60mV and 80mV. One of ordinary skill in the art would not be able to determine the onset EMG response amplitude, because if the predetermined value is 60mV or 80mV, the onset value would not be a value between 60mV and 80mV, because the onset value must be higher than the predetermined level. Furthermore, the current specification fails to clearly disclose the necessity of the range of 60mV to 80mV as the predetermined value. Resting potential of the membrane is normally in the range of -60mV to -80mV. A predetermined value (threshold) in the range of 60-80mV would yield the zero potential of the axon. The

current specification fails to disclose if the predetermined value of 60mV to 80mV is a value different from the zero potential of the axon (for instance a value of the positive potential), or if the 60mV to 80mV range is in fact the zero potential of the axon. If the 60mV to 80mV range is the positive potential, the disclosed range in both the claim and specification is a physical impossibility. The positive potential (at the peak) of an axon is in the range of 20-50mV.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 discloses the predetermined value has a range of 60mV to 80mV. Based on the current specification, it is unclear to the Examiner if the claimed range is the predetermined value, or if the range is the range of the onset EMG response.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-14 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558) in view of Calancie et al (Stimulus-Evoked

EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) in view of Katims (5,806,522).

Neubardt discloses a method for spinal screw insertion and further discloses applying an electrical stimulus to the first aspect of the bone; the electrical stimulus is emitted from an electrode disposed on the distal end of at least one of a probe and surgical tool; applying an electrical stimulus comprises applying a plurality of electrical stimulus pulses; the bone is disposed within one of the cervical, thoracic, and lumbar region of the patient's spine; the spinal nerve exits from successive vertebrae within one of the cervical, thoracic, and lumbar region of the patient's spine; the first aspect of the bone comprises a region within a pedicle in contact with a pedicle screw; and applying an electrical stimulus to the first aspect of the bone comprises applying the electrical stimulus to a proximal end of a bone screw inserted into the first aspect of the bone. See Figures 3 and 4; and Column 8, lines 59-67.

Neubardt however fails to disclose electrically monitoring a plurality of leg muscle myotome locations via a plurality of EMG sensors, at least one of the leg muscle myotome locations being associated with the spinal nerve; automatically determining an onset neuro-muscular response to the application of the electrical stimulus to the first aspect of the bone by automatically increasing the electrical stimulus until the onset neuro-muscular response is detected by the EMG sensors outputting a signal having an amplitude greater than a predetermined value; communicating to a surgeon operating on the patient’s spine an onset electrical stimulus level which causes the onset neuro-muscular response; the plurality of electrical stimulus pulses comprises current pulses

that increase over time; the plurality of electrical stimulus pulses comprises current pulses that vary incrementally; the plurality of electrical stimulus pulses comprises current pulses varied incrementally within a range from 0.5 to 32.0 milliamps; the onset neuro-muscular response is an electromyography response from a muscle coupled to the spinal nerve; electrically monitoring the muscle myotome is performed through the use of a needle electrodes electrically coupled to the muscle myotome; the muscle myotome is disposed in one of the patient's legs; and the onset neuro-muscular response is determined by assessing whether the neuro-muscular response is greater than a predetermined onset level and increasing the electrical stimulus until the determined neuro-muscular response is greater than the predetermined onset level.

Calancie et al disclose a means for determining the evoked EMG during spinal fusion surgery and further disclose electrically monitoring a plurality of leg muscle myotome locations via a plurality of EMG sensors, at least one of the leg muscle myotome locations being associated with the spinal nerve; automatically determining an onset neuro-muscular response to the application of the electrical stimulus to the first aspect of the bone by automatically increasing the electrical stimulus until the onset neuro-muscular response is detected by the EMG sensors outputting a signal having an amplitude greater than a predetermined value; communicating to a surgeon operating on the patient’s spine an onset electrical stimulus level which causes the onset neuro-muscular response; the plurality of electrical stimulus pulses comprises current pulses that increase over time; the plurality of electrical stimulus pulses comprises current pulses that vary incrementally; the plurality of electrical stimulus pulses comprises

current pulses varied incrementally within a range from 0.5 to 32.0 milliamps; the onset neuro-muscular response is an electromyography response from a muscle coupled to the spinal nerve; electrically monitoring the muscle myotome is performed through the use of a needle electrodes electrically coupled to the muscle myotome; the muscle myotome is disposed in one of the patient's legs; and the onset neuro-muscular response is determined by assessing whether the neuro-muscular response is greater than a predetermined onset level and increasing the electrical stimulus until the determined neuro-muscular response is greater than the predetermined onset level.. See pages 2780-2782.

Since both Neubardt and Calancie et al disclose means for monitoring stimulus evoked responses, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Neubardt to include the use of electrically monitoring the EMG response, as per the teachings of Calancie et al, since it would provide a more accurate means of monitoring the status of the pedicle screw in relation to the spinal nerve. It also would have been obvious to one of ordinary skill in the art to apply the monitoring means to the arms of the patient when working on the cervical spine.

Neubardt and Calancie et al however fail to disclose automatically increasing the electrical stimulus until a response is detected using a neurophysiology system; communicating to the surgeon includes visually displaying to the surgeon an intensity level representing the onset electrical stimulus level causing the onset neuromuscular response; and visually displaying involves the use of an integrated display.

Katims discloses an automated current perception threshold determination device and further discloses automatically increasing the electrical stimulus until a response is detected using a neurophysiology system; communicating to the surgeon includes visually displaying to the surgeon an intensity level representing the onset electrical stimulus level causing the onset neuromuscular response; and visually displaying involves the use of an integrated display. See Figure 2; Column 7, lines 19-32; and Column 34, lines 9-23.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to change the manual operation as disclosed by the combination of Neubardt and Calancie et al, to an automatic operation, as taught by Katims, since the replacement of a manual operation with an automatic operation is a design consideration within the skill of the art. See In re Venner, 262 F.2d 91, 120 USPQ 192 (CCPA 1955).

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558), Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) and Katims (5,806,522) as applied to claim 14 above, and further in view of Epstein et al (6,259,945 B1).

Neubardt, Calancie et al and Katims, as discussed above, disclose a means of monitoring the muscle response of a stimulated nerve during spinal surgery, but fail to disclose visually displaying includes illuminating lights.

Epstein et al disclose a means for locating a nerve and further disclose the use of illuminating lights to convey the electrical stimulus current level that elicits an onset muscle response. See Column 5, lines 6-11.

Since Neubardt, Calancie et al and Katims disclose means for visually alerting a user to the EMG status, but fail to disclose colored lights representing the measured status, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Neubardt, Calancie et al and Katims to include the use of illuminating lights for indicating the current level that elicits an onset response, as per the teachings of Epstein et al, since lights provide an alternative means of providing information to a user.

14. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558), Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) and Katims (5,806,522) as applied to claim 14 above, and further in view of Epstein et al (6,259,945 B1) in view of Chen et al (6,138,681).

Neubardt, Calancie et al and Katims, as discussed above, disclose a means of monitoring the muscle response of a stimulated nerve during spinal surgery, but fail to disclose displaying different lights on the display when the current value is below a predetermined level, and each light corresponds to a warning to the surgeon.

Epstein et al, as discussed above, disclose a means of using different lights to indicate the stimulus level and the lights provide a warning to the surgeon.

Since Neubardt, Calancie et al and Katims disclose means for visually alerting a user to the EMG status, but fail to disclose colored lights representing the measured status, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Neubardt, Calancie et al and Katims to include the use of different lights to indicate the stimulus level and provide a warning to the surgeon, as per the teachings of Epstein et al, since utilizing lights on a medical monitor also provides an easily readable indicator to the surgeon performing the medical procedure.

Neubardt, Calancie et al, Katims and Epstein et al however fail to explicitly disclose the use of different colored lights on the device to indicate a signal value below a baseline.

Chen et al disclose a means for indicating the alignment of an external medical device to an internal medical device, and further disclose the use of different colored lights on the device to indicate a signal value below a baseline (the lights indicate a baseline; if the transmitter is close to the implanted device, a light will be illuminated; the closer the transmitter is to the implanted device, more lights will be illuminated). See Column 8, lines 5-11.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Neubardt, Calancie et al, Katims and Epstein et al, to include the use of colored lights to provide an indication of a signal below a baseline, as per the teachings of Chen et al, since it would provide a visual indication means that is easily interpreted by a user.

15. Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558), Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) and Katims (5,806,522) as applied to claim 1 above, and further in view of Raymond et al (5,284,153).

Neubardt, Calancie et al and Katims, as discussed above, disclose a means for monitoring the EMG response to a stimulated pedicle screw, but fail to disclose the use of an audible indicator for indicating an intensity level of the response; sounding an alarm; varying the volume of the alarm; and varying the frequency of the alarm.

Raymond et al disclose a means of protecting nerves from injury during surgery, and further disclose the use of an audible indicator for indicating an intensity level of the response; sounding an alarm; varying the volume of the alarm; and varying the frequency of the alarm. See Column 7, lines 8-16.

It would have been obvious to one of ordinary skill in the art to modify the combination of Neubardt, Calancie et al and Katims to include the use of an audible indicator, as per the teachings of Raymond et al, since it would provide an additional means of alerting the user.

Response to Arguments

16. Applicant's arguments filed November 13, 2009 have been fully considered but they are not persuasive.

The Applicants argue the current combination fail to teach the currently amended claims. In particular, the combination fails to teach "**determining an onset neuro-**

muscular response to the application of said electrical stimulus to said first aspect of said bone by automatically increasing said electrical stimulus in constant increments until said onset neuro-muscular response is detected by one or more of the EMG sensor electrodes outputting an EMG signal having an amplitude value greater that a predetermined value." The Applicants further argue Calancie et al fail to teach the "constant increments" and EMG electrodes “outputting an EMG signal having an amplitude greater than a predetermined value". The Examiner respectfully disagrees. As stated in the above rejection, Katims teaches the "constant increments" of an electrical stimulus, in Column 7, lines 19-32; and Column 34, lines 9-23. The automatic determination of a threshold response to an applied electrical stimulus inherently requires a constantly incrementing the stimulus level until a response is elicited. Calancie et al inherently discloses the claim limitation: EMG electrodes “outputting an EMG signal having an amplitude greater than a predetermined value". Based on the current claim language, the “predetermined value” can be interpreted as zero. Since Calancie et al acquires an evoked EMG response, the EMG response inherently has an amplitude greater than zero.

The Applicants also argue the combination fails to also teach "displaying on a display device of said neurophysiology system that is viewable by a surgeon operating on the patient's spine an onset electrical stimulus current level which causes said onset neuro-muscular response." The Examiner respectfully disagrees. Calancie et al teach the use of a means to apply a stimulus until an EMG response was seen. Calancie et al inherently teach the use of a monitor that has the ability to display the stimulus intensity

(since the stimulus is increased to elicit a response), and display the EMG response, such that the electrophysiologist can read the response and alert the surgeon. Furthermore, the current claim language only requires the display to be capable of being viewed by the surgeon. The surgeon has the ability to view the monitor in Calancie et al. Katims also disclose a monitor that displays the stimulation intensity level and can be used to determine nerve responses to an electrical stimulus. Likewise, the surgeon has the ability to view the display of the monitor of Katims to view the EMG response of the applied stimulus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736